

July 20, 2011

Terry Dwelle, M.D., M.P.H.T.M.
State Health Officer
North Dakota Department of Health
State Capitol
600 East Boulevard Avenue
Bismarck, ND 58505-0200

Dear Dr. Dwelle:

On June 16, 2011, the Management Review Board (MRB) met to consider the proposed final Integrated Materials Performance Evaluation Program (IMPEP) report on the North Dakota Agreement State Program. The MRB found the North Dakota Agreement State Program adequate, but needs improvement, to protect public health and safety, and compatible with the U.S. Nuclear Regulatory Commission's (NRC) program. Because of the significance of the findings, the MRB determined that the North Dakota Program should undergo a period of Heightened Oversight. Heightened Oversight is an increased monitoring process the NRC uses to follow the progress of improvement needed in an Agreement State program. It involves preparation of a program improvement plan, bimonthly conference calls, and submission of status reports prior to each call with the appropriate North Dakota and NRC managers and staff members.

Section 4.0, page 18, of the enclosed final report contains a summary of the review team's findings and recommendations for the North Dakota Agreement State Program. We request that you prepare and submit a program improvement plan as part of your response to the review team's recommendations. I ask that you have your staff discuss the required elements of this plan with Mr. Terrence Reis, Acting Director, Division of Materials Safety and State Agreements, Office of Federal and State Materials and Environmental Management Programs, to ensure that the "get-well" path and measures of success are clearly identified. The plan should be submitted within 30 days of receipt of this letter. Upon review of your program improvement plan, NRC staff will schedule the first conference call. The initial conference call should be scheduled and conducted no later than October 1, 2011.

T. Dwelle

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Based on the results of the current IMPEP review, a Periodic Meeting will be held within 1 year to assess the State's progress in addressing the open recommendations, and a follow-up IMPEP review take place approximately 1 year following the Periodic Meeting (2 years from current IMPEP). The MRB believes that the performance of a follow-up IMPEP at approximately 2 years from the current IMPEP will allow the State sufficient time to correct programmatic issues identified during the review. The follow-up review will cover the State's actions in response to the recommendations in the enclosed final report.

I appreciate the courtesy and cooperation extended to the IMPEP team during the review. I also wish to acknowledge your continued support for the Agreement State Program. I look forward to our agencies continuing to work cooperatively in the future.

Sincerely,

/RA/

Michael F. Weber
Deputy Executive Director for Materials, Waste,
Research, State, Tribal, and Compliance Programs
Office of the Executive Director for Operations

Enclosure:
North Dakota Final IMPEP Report

cc w/encl.: Terry O'Clair, Director
Division of Air Quality



INTEGRATED MATERIALS PERFORMANCE EVALUATION PROGRAM
REVIEW OF THE NORTH DAKOTA AGREEMENT STATE PROGRAM

APRIL 4-8, 2011

FINAL REPORT

EXECUTIVE SUMMARY

This report presents the results of the Integrated Materials Performance Evaluation Program (IMPEP) review of the North Dakota Agreement State Program. The review was conducted during the period of April 4-8, 2011, by a review team composed of technical staff members from the U.S. Nuclear Regulatory Commission (NRC) and the Commonwealth of Kentucky.

The Management Review Board (MRB) met on June 16, 2011, to consider the proposed final report. Based on the results of this review, the review team recommended, and the MRB agreed, that North Dakota's performance be found unsatisfactory for one performance indicator reviewed; satisfactory, but needs improvement for three performance indicators reviewed; and satisfactory for two performance indicators reviewed.

The review team made 11 recommendations regarding the performance of the North Dakota Agreement State Program. These recommendations, which are briefly described below, included areas for improvement to correct identified performance deficiencies and weaknesses in North Dakota's Agreement State Program. The review team recommends that the State: (1) update its procedures to memorialize the policies and practices of the Agreement State program and examine staffing options to effectively implement the program.; (2) ensure that initial inspections are performed at the prescribed interval; (3) ensure that inspection findings are communicated to licensees in a timely manner; (4) ensure that sufficient information pertaining to inspections is appropriately documented and that items of non-compliance are appropriately communicated to licensees; (5) obtain additional training to enhance inspection skills; (6) ensure that licensing actions are adequately documented and consistent with the regulations and licensing guidance; (7) provide additional training regarding the technical review of licensing actions and correct deficiencies identified in the licensing casework review; (8) take measures to determine and document the basis of confidence that radioactive materials will be used as intended and as described in applications or amendment requests; (9) take measures to assure that financial assurance requirements are properly implemented; (10) take measures to strengthen its incident response program; and (11) take measures to strengthen its allegation program.

The review team recommended, and the MRB agreed, that the North Dakota Agreement State Program be found adequate, but needs improvement, to protect public health and safety, and compatible with NRC's program.

Based on the results of the current IMPEP review, the review team recommended, and the MRB agreed, that NRC initiate a period of Heightened Oversight for North Dakota. The review team further recommended, and the MRB agreed, that a Periodic Meeting be held within 1 year and that a follow-up IMPEP review take place approximately 1 year following the Periodic Meeting.

1.0 INTRODUCTION

Under Section 274 of the Atomic Energy Act (AEA) of 1954, as amended, the U.S. Nuclear Regulatory Commission (NRC) has programmatic responsibility to periodically review the actions of the Agreement States to comply with the requirements of the AEA to continue to maintain adequate and compatible programs. The current review process under the Integrated Materials Performance Evaluation Program (IMPEP) is conducted with State staff participation under the National Materials Program.

This report presents the results of the review of the North Dakota Agreement State Program. The onsite portion of the review was conducted during the period of April 4-8, 2011, by a review team composed of technical staff members from the NRC and the Commonwealth of Kentucky. Team members are identified in Appendix A. The review was conducted in accordance with the "Implementation of the Integrated Materials Performance Evaluation Program and Rescission of Final General Statement of Policy," published in the *Federal Register* on October 16, 1997, and NRC Management Directive 5.6, "Integrated Materials Performance Evaluation Program (IMPEP)," dated February 26, 2004. Preliminary results of the review, which covered the period of April 20, 2007, to April 8, 2011, were discussed with North Dakota managers on the last day of the review.

A draft of this report was issued to North Dakota for factual comment on May 2, 2011. The State responded by electronic mail dated May 31, 2011, and a revised response dated June 13, 2011, from Daniel E. Harman, Manager, Division of Air Quality. Copies of the State's responses are included as an Attachment to this report. The Management Review Board (MRB) met on June 16, 2011, to consider the proposed final report. The MRB found the North Dakota Agreement State Program adequate to protect public health and safety, but needs improvement and compatible with NRC's program.

The North Dakota Agreement State Program is administered by the Radiation and Indoor Air Branch (the Branch), in the Division of Air Quality (the Division). The Division is part of the North Dakota Department of Health (the Department). Organizational charts for the Branch, the Division, and the Department are included as Appendix B.

At the time of the review, the North Dakota Agreement State Program regulated approximately 76 specific licenses authorizing byproduct, source, and certain special nuclear materials. The review focused on the radioactive materials program as it is carried out under the Section 274b (of the Atomic Energy Act of 1954, as amended) Agreement between the NRC and the State of North Dakota.

In preparation for the review, a questionnaire addressing the common and applicable non-common performance indicators was sent to the Branch on December 21, 2010. The Branch provided its response to the questionnaire via email on March 19, 2011, with supplemental information provided on March 21, 2011. A publicly available version of the questionnaire response can be found in NRC's Agencywide Documents Access and Management System (ADAMS) using the Accession Number ML110810051.

The review team's general approach for conduct of this review consisted of: (1) examination of the Branch's response to the questionnaire; (2) review of applicable North Dakota statutes and

regulations; (3) analysis of quantitative information from the Branch's databases; (4) technical review of selected regulatory actions; (5) field accompaniments of two inspectors; and (6) interviews with staff and managers. The review team evaluated the information gathered against the established criteria for each common and the applicable non-common performance indicator and made a preliminary assessment of the North Dakota Agreement State Program's performance.

Results of the review for the common performance indicators are presented in Section 2.0. Section 3.0 details the results of the review of the applicable non-common performance indicators, and Section 4.0 summarizes the review team's findings and recommendations. The review team's recommendations are comments that relate directly to the Division's performance. A response is requested from the State to all recommendations in the final report.

2.0 COMMON PERFORMANCE INDICATORS

Five common performance indicators are used to review NRC Regional and Agreement State radioactive materials programs. These indicators are: (1) Technical Staffing and Training, (2) Status of Materials Inspection Program, (3) Technical Quality of Inspections, (4) Technical Quality of Licensing Actions, and (5) Technical Quality of Incident and Allegation Activities.

2.1 Technical Staffing and Training

Issues central to the evaluation of this indicator include the Branch's staffing level and staff turnover, as well as the technical qualifications and training histories of the staff. To evaluate these issues, the review team examined the Branch's questionnaire response relative to this indicator; interviewed managers and staff, reviewed job descriptions and training records, and considered any workload backlogs.

When fully staffed, the North Dakota Agreement State Program is composed of a manager and two technical staff. The manager and technical staff conduct inspections, perform licensing actions, and respond to incidents and allegations based on individual qualifications. The manager and technical staff members have at least a bachelor's degree in a physical or life science or engineering. Based on information provided by the Branch, the review team estimated that the Division expends approximately 2.8 to 3.0 full-time equivalents (FTE) to administer the Agreement State program, which includes support from the Division Director and some limited administrative support.

During the review period, there was a Branch management change as well as several technical staff changes. Immediately following the previous IMPEP review, the Branch manager, who had several years of radioactive materials experience, left the Division. Within about two months, the manager position was filled with the current Branch manager. The current Branch manager has many years of experience with the State, but has only been involved with the radioactive materials program since becoming the Branch manager approximately four years ago, and has limited prior experience with radioactive materials. Furthermore, the technical staff experienced significant turnover during the review period. During the review period, the Branch has been able to readily fill vacancies but has not been able to retain staff. The two technical staff present during the previous IMPEP review both left the Branch. In both cases, the vacancies were promptly filled. The two technical staff members that were hired to fill the

vacancies also left the Branch. One individual left after approximately 11 months and the second individual left after approximately two and a half years. Both of these vacancies were promptly filled. The two current technical staff members have appropriate education and background but no prior regulatory experience. One individual has been with the Branch for approximately one year and four months and the other individual for approximately eight months. The review team explored the reason for the high staff turnover and concluded that staff had left the program for varying reasons, including leaving for employment with other Agreement State programs, for other higher paying jobs, and for personal reasons.

During the review period, it was recognized by the Branch that staff turnover and inexperience of new staff members could impact the quality of the State's radioactive materials program. Consequently, NRC had coordinated with the State of Minnesota to provide support to North Dakota. As a result, experienced staff from the Minnesota Agreement State program provided on-the-job training and inspection assistance to North Dakota staff, including the Branch manager. Additionally, the Branch manager and one of the former North Dakota technical staff traveled to Minnesota to observe inspection activities. Other than the current Branch manager, the North Dakota technical staff members who were recipients of this additional training are no longer with the Branch.

Training and qualification requirements for Branch staff had been established in the North Dakota Radiation Control Program Administrative Procedures Manual. Training and qualification is documented through the use of a "Training Regimen Checklist." This is consistent with the requirements in the NRC/Organization of Agreement States Training Working Group Report and NRC's Inspection Manual Chapter (IMC) 1246, "Formal Qualification Programs in the Nuclear Material Safety and Safeguards Program Area."

The Branch's qualification process consists of formal coursework, observations of inspections, and supervised inspections. After supervised inspections are performed for different license types, there is a "sign-off" that indicates that the individual is authorized to perform inspections independently. The Branch manager, who also performs inspections, has completed all formal coursework. One current member of the technical staff is making steady progress toward completion of formal coursework and was authorized to perform several types of inspections independently. The most recent member of the technical staff has begun the qualification process by taking formal coursework but has not yet been authorized to perform independent inspections.

Given the high rate of turnover in the Branch, the review team discussed with the Branch manager and Division Director the value of having some type of knowledge management program. Because of staff turnover during the review period, the Branch manager has had to spend a significant portion of his time implementing the licensing and inspection program. This has not left the Branch manager with sufficient time to "manage" and develop the program. In January 2011, the Branch manager began updating some Branch procedures, however there remains a significant amount of work necessary to develop a sustained program in the event of further staff losses.

With a small program, the Branch has often relied on verbal communication to implement new policies and practices. This practice can be effective in a small program where there is limited turnover; however, in a program with a high turnover rate, the documentation of policies and

practices is very important. The review team determined that a majority of the program's knowledge was lost with the departure of the former Branch manager and with other former members of the technical staff. Some portion of the program's knowledge resides in the Division Director and the Branch manager. In the event of one of these individuals leaving the Division, there is a danger in the further loss of program knowledge. This concern will need to be addressed to ensure the long-term health of the Agreement State program. Programmatic knowledge retention therefore, is not only dependent on having documented tools to implement the program but is also dependent on retaining qualified personnel and/or having sufficient depth in staffing to effectively implement the program. The review team recommends that the State: (1) update its existing procedures and develop new procedures, as necessary, to memorialize the policies and practices of the Agreement State program and to serve as a knowledge management tool, and (2) examine options to increase staff retention and/or develop sufficient depth in staffing to effectively implement the program.

The review team discussed the appropriate finding for this indicator. The review team considered a finding of satisfactory, but needs improvement, because of the chronic issue of staff turnover. In reaching a recommendation for this indicator, the review team recognized that the Branch is currently fully staffed with individuals that possess both education and background that will serve as a strong base toward becoming fully qualified inspectors and license reviewers. The review team believes that if provided with additional training, including on-the-job training, these individuals can excel and be successful in carrying out the program. The team did however identify specific training issues related to the technical quality of inspections and technical quality of licensing actions. These are described in Section 2.3, "Technical Quality of Inspections" and Section 2.4, "Technical Quality of Licensing Actions," respectively. Because the review team addressed the need for additional training in its review of the other indicators, the review team believed that a finding of satisfactory was the more appropriate finding for this indicator.

Based on the IMPEP evaluation criteria, the review team recommended, and the MRB agreed, that North Dakota's performance with respect to the indicator, Technical Staffing and Training, be found satisfactory.

2.2 Status of Materials Inspection Program

The review team focused on five factors while reviewing this indicator: inspection frequency, overdue inspections, initial inspections of new licenses, timely dispatch of inspection findings to licensees, and performance of reciprocity inspections. The review team's evaluation was based on the Branch's questionnaire response relative to this indicator, data gathered from the Branch's database, examination of completed inspection casework, and interviews with the Branch manager and current technical staff members.

The review team verified the Branch's inspection frequencies for various license types are as frequent as those found in NRC's Inspection Manual Chapter (IMC) 2800, "Materials Inspection Program." During the review period, the Branch corrected the inspection frequency for its high-dose rate remote afterloader licensees from every 3 years to every 2 years as found in NRC's IMC 2800. On January 1, 2011, the Branch adopted as policy the recent revision to NRC's IMC 2800, which was issued on November 15, 2010. The Branch had originally designated the radionuclide production (cyclotron) license to be performed on a 5 year frequency; however to

be consistent with the recent revision to NRC's IMC 2800, the frequency was recently changed by the Branch to every 2 years.

The Branch's database had limited capabilities for retrieval of inspection data from the entire review period. For most inspections performed by the Branch, the data from the most recent inspection could be retrieved, resulting in the review team being able to review data from approximately the last 1-3 years of the review period. Therefore, in order to facilitate its review of this indicator, the review team not only verified the Branch's inspection timeliness based on the information that could be obtained from the database but also performed interviews with staff members and reviewed the inspection case work for determination of Priority 1, 2, 3, and initial inspections. As could be determined based on the information provided by the Branch, over the review period, the Branch performed 23 Priority 1, 2, and 3 inspections, of which 2 were performed overdue (i.e. greater than 25% of the assigned inspection frequency) and none were overdue at the time of the review. Initial inspections are to be conducted within 12 months of license issuance. The review team found that 10 new licenses had been issued during the review period but that five were not yet due for inspection at the time of the review. Of the remaining five new licenses, three initial inspections were conducted on time, one was conducted overdue (i.e. greater than 1 year after issuance of the license), and one was overdue at the time of the review. Overall, the review team calculated that the Branch performed 15 percent of its inspections overdue during the review period. The review team concluded that the percent of inspections overdue was caused, in part, due to issues associated with chronic staff turnover, deficiencies in the data entered into the Branch's database, and limitations of the Branch's database to serve as an inspection planning and scheduling tool.

During the previous IMPEP review, the Branch struggled with this indicator to meet the inspection timeliness criteria. This was due, in part, to a practice of setting the inspection due date as the end of the 25% window date. During the review period, the Branch corrected this practice and set the inspection due date as the inspection date plus 1, 2, or 3 years as appropriate. This change helped correct the timeliness issue for Priority 1, 2, and 3 inspections. However, the Branch did not identify that initial inspections need to be performed within 1 year of the license issue date. Additionally, when new licenses were issued, the Branch did not have a routine practice of setting a due date in its database. As a result, in some cases, the due date was left blank and the initial inspections never appeared on the due list. The review team recommends that the State take measures to ensure that initial inspections are performed at the interval prescribed in NRC's IMC 2800.

The review team verified the Branch's performance of all initial inspections of licensees subject to the Increased Controls no later than three years after the date of implementation of the Increased Controls. When the Increased Controls were issued, the Branch had eight licensees subject to the Increased Controls. At the time of the review, the Branch had 11 licensees subject to the Increased Controls. The State implemented the Increased Controls requirements through license conditions and all initial inspections of the Increased Controls were to be completed before the end of 2008. The review team found that one licensee subject to the initial round of Increased Controls inspections had two locations subject to the requirements. The review team found that the Branch's database did not allow for the tracking of inspection information for licenses that have multiple locations of use/storage. The review team conducted a search of the Branch's hard copy inspection records for the licensee in question, and found that one of the locations had been inspected against the Increased Controls but there was no

record of any kind that the second location had been inspected by the Branch since 1999, prior to the issuance of the Increased Controls. Further review and follow-up by the review team found evidence, some of which was anecdotal, that the second location had been inspected in 2007 and again in 2008. However, the results of these inspections were not documented and it is not clear whether the inspections addressed the Increased Controls requirements or if they only addressed health and safety requirements. None of the individuals who were associated with performing the missing inspections were with the Branch at the time of the review. This matter was discussed with the Branch manager, who acknowledged that there was no record of the inspections having been performed or any documentation of the results of the inspections. As a result, the Branch manager made a plan to conduct an inspection of the location, including the licensee's implementation of the Increased Controls, for the week following the review.

The review team evaluated the Branch's timeliness in issuing inspection findings. The Branch generally communicates these findings to licensees by issuing a "Letter of Compliance" or a "Letter of Apparent Non-Compliance." The review team found that, based on the information provided from the Branch's database 21 of 55 of the Branch's inspection findings were issued greater than 30 days following the date of the inspection. This was further supported by a review of the inspection case files. The review team found that inspection findings related to one inspection that identified significant health and safety issues were not issued by the Branch until 38 days following the inspection. The review team discussed with the Branch manager the need to document the reasons for any delays in issuing inspection findings to licensees, especially when matters important to health and safety or security are being addressed. The review team recommends that the State take measures to ensure that inspection findings are communicated to licensees within 30 days of the date of the inspection.

During the review period the Branch granted approximately 42 reciprocity requests that they identified as candidates for inspection as described in NRC's IMC 1220 "Processing of NRC Form 241 and Inspection of Agreement State Licensees Operating under 10 CFR 150.20." Based on the Branch's questionnaire response and review of documents provided during the review, the review team found that the Branch was unable to consistently perform inspections of 20 percent of the reciprocity licensees annually. During one year of the review period, the Branch was unable to perform any inspections of licensees operating under reciprocity. During each of the other years of the review period, the Branch performed inspections of: 30 percent, 11 percent, and 18 percent of licensees operating under reciprocity. Historically the Branch has had difficulty achieving the 20 percent described in NRC's IMC 2800 due, in large part, to the geographical location of reciprocity activities (e.g. well logging activities are prevalent in the far north and western portions of the State), and challenges presented by weather conditions. During the review period, an additional challenge in performing reciprocity inspections was also due in part to staff turnover.

Many of the issues identified above (e.g. timeliness of initial inspections, performance of inspections of multiple use locations, timeliness of issuance of inspection findings) could be attributed, in part, to deficiencies associated with the Branch's database. The review team found several errors associated with the information contained in the Branch's database. In some cases, the inspection due date was blank and therefore the inspection never appeared on the "to do" list of inspections. If the quality of the information in the database was improved and some features were enhanced, it could be a very useful tool for the Branch. Another matter that contributed to the issues identified above is lack of management oversight. Due to the technical

staff turnover issues described in Section 2.1, the Branch manager has been filling a more technical staff-type role and has had to spend substantial time either performing or assisting with inspections and training of new staff members. As a result, the Branch manager has not been able to sufficiently oversee the Branch activities from a management perspective (e.g. plan and track Branch inspection activities). The Branch manager indicated that there are plans to review the information contained in the database and develop additional useful features to prevent recurrence of some of the identified problems. The Branch manager believes that with the current stability of the technical staff, he will be able to devote more time to planning and overseeing Branch activities.

Based on the IMPEP evaluation criteria, the review team recommended, and the MRB agreed, that North Dakota's performance with respect to the indicator, Status of Materials Inspection Program, be found satisfactory, but needs improvement.

2.3 Technical Quality of Inspections

The review team evaluated 13 inspection reports that included inspection records, enforcement documentation and letters to licensees, and interviewed the Branch manager and technical staff members who were responsible for some of the radioactive materials inspections conducted during the review period. The casework reviewed covered a wide variety of inspection types, including academic broad scope, radionuclide production (cyclotron), industrial radiography, self-shielded irradiators, and medical-written directives required, and also included inspections conducted by the current Branch manager and one technical staff member as well as 3 former technical staff members. Appendix C lists the inspection casework files reviewed as well as the results of the inspector accompaniments performed by the review team.

Based on the review of casework, the review team noted that some inspections did not address all aspects of the licensees' radiation safety programs. Based on the evaluation of casework, the review team determined that inspection reports were frequently not thorough, were incomplete, inconsistent, and did not contain sufficient documentation to ensure that licensees' performance with respect to health, safety, and security were acceptable. Additionally, inspection documentation did not always address review by the current inspector of items of non-compliance that were identified during previous inspections.

If potential non-compliance items are identified during an inspection, the Branch issues a Letter of Apparent Non-Compliance. The letters are dispatched to licensees after the Branch manager reviews the inspection record and the accompanying letter. Such letters are submitted to the Division Director for signature and issuance to the licensee. The review team found that some Letters of Apparent Non-Compliance did not address items of non-compliance that were documented in the inspection records. Additionally, some letters did not provide sufficient detail to facilitate appropriate licensee corrective actions. The review team found that some inspection documentation did not always support identified items of non-compliance. When items of non-compliance are not well supported in the inspection record, it is difficult to follow-up on these items during future inspections. The review team recommends that the State: (1) take measures to ensure that sufficient information pertaining to inspection observations and identified non-compliances is documented in inspection records and in letters to licensees and that these documents be appropriately reviewed by management, prior to issuance, for thoroughness and consistency, and (2) develop and implement a plan to address comments

noted in Appendix C related to identified items of non-compliance that were not included in findings that were dispatched to licensees.

The Branch's written policy was that at least 10% of all field inspections include the Branch manager or Division Director. The review team found that during the review period, the Branch manager had accompanied all qualified staff performing radioactive materials inspections on an annual basis. During some accompaniments, the Branch manager participated in inspection activities as well as reviewed inspector performance.

The review team noted that the Branch maintained appropriately calibrated survey instruments to support the inspection program. The Branch possessed two kits that each contained a survey meter with several detector/probe types for performing surveys of various radiological conditions. The instrumentation is calibrated by an outside vendor according to the manufacturer's recommendations. The Branch manager noted that additional survey meters were going to be acquired concurrent with the replacement of some older out-of-service instrumentation.

A review team member accompanied the Branch manager and one member of the technical staff during inspections the week of January 31, 2011. Because performance issues were identified by the review team member during the accompaniments, a second week of accompaniments was performed the week of March 14, 2011. In accordance with the State's training program, the Branch manager is a fully qualified inspector. The other individual that was accompanied was not a fully qualified inspector but was qualified to independently perform inspections of most license types. The inspections selected were in areas the inspector was qualified to inspect. The license types inspected as part of the accompaniments included a facility that produced radionuclides with a cyclotron, academic broad scope, industrial radiography, and medical facilities that performed various diagnostic and therapeutic procedures, including activities involving radioiodine therapy, permanent implant brachytherapy, and high dose-rate remote afterloader brachytherapy. Two of the inspections included a review of the licensee's implementation of the Increased Controls. The accompaniments and associated comments are identified in Appendix C.

In January 2011, the Branch moved from a more compliance-driven inspection procedure to a performance-based inspection procedure. During the accompaniments, the inspectors made a strong effort to incorporate interviews with appropriate personnel and performance observations into their inspection activities. However, the inspectors often did not adequately follow-up on potential items of non-compliance that were observed during the performance reviews. For some areas inspected, the inspectors did not have sufficient familiarity with the regulations or with certain regulatory requirements. These areas included regulatory requirements related to procedures requiring written directives, patient release criteria, and the Increased Controls. Both inspectors had done some level of preparation prior to the inspections, but in some cases, the prior review of authorized activities, license conditions, and inspection history was not adequate. Although both inspectors have attended formal training courses, due to staff turnover issues neither has received much on-the-job training or mentoring by experienced inspectors.

During the observed inspections, the inspectors did not understand the importance of performing independent radiation surveys of licensed activities. When independent radiation surveys were performed, the inspectors did not use appropriate techniques. Furthermore, the

inspectors did not have an adequate understanding of proper operation of their radiation detection and measurement instrumentation. There was a lack of understanding of how to source-check the Branch's instrumentation to verify operability, a lack of understanding of the efficiencies of the Branch's instrumentation associated with the detection of various radionuclides, and there were general issues with basic operation of the equipment.

The inspectors were not adequately prepared for the inspection of the radionuclide production (cyclotron) facility. The inspectors did not have familiarity with the licensed cyclotron operations or with radiation safety and health physics issues associated with cyclotron operations. As a result, the inspection did not identify several health physics and radiation safety issues associated with these risk-significant operations. As an example, the inspector accepted the licensee's explanation that an alarm condition on an in-line monitor was due to it malfunctioning. However, the alarm condition was likely due to irradiated targets being stored improperly in the vicinity of the radiation monitor. Had the inspectors been performing appropriate independent radiation surveys, they would have identified this condition and the resulting radiation safety hazard.

During the observed inspections of the Increased Controls and Fingerprinting requirements, the inspectors did not have an adequate understanding of the requirements and therefore had difficulty assessing licensee compliance with the requirements. In one case, the inspector did not identify or understand the security significance of an item of non-compliance. During the exit meeting with licensee management, the inspector was unable to clearly articulate the applicable requirements and was unable to explain to the licensee what actions could be taken to correct the identified deficiencies.

The review team member's observations were shared with the inspectors throughout the accompaniment process. Additionally, the review team member's observations were discussed with the Division Director. When notified of these observations, the Division Director indicated that past issues related to staff turnover had likely contributed to the issues observed during the inspections. The review team member noted that the quality of inspections had somewhat improved from the first week of observed inspections to the second week, and that the inspectors had learned from the earlier discussions with the review team member and had incorporated some changes to their inspections.

The review team recommends that the State obtain additional training (formal and on-the-job, as appropriate) for the Branch manager and members of the technical staff to enhance inspection skills, particularly with regards to: (1) radiation safety issues associated with cyclotron operations, and (2) proper operation and use of radiation survey and measurement instrumentation.

At the conclusion of the review, the review team discussed with the Division Director and Branch manager that their preliminary recommendation was that this indicator be found satisfactory, but needs improvement. However, upon further review of the totality of information gathered during the review (e.g. inspection case files, inspector accompaniments), the review team re-evaluated the criteria in MD 5.6 and believes that a finding of unsatisfactory is more appropriate for this indicator. In particular, the inspection case files that were reviewed indicated problems with completeness, technical quality, consistency, attention to health and safety/security, and management review throughout the review period and across former

inspectors as well as current inspectors. Additionally, the inspector accompaniments indicated problems with completeness, technical quality, and attention to health and safety/security. One individual that was accompanied has been with the program for 4 years and was partially responsible for training other inspectors during the review period. Based on the review team member's observations during the inspector accompaniments, it was evident that the observed inspection deficiencies have existed throughout the review period and are indicative of a programmatic and chronic problem rather than an isolated occurrence or a periodic decline in performance. Therefore, based on the review of the inspection case files and the inspector accompaniments, the review team believes that the issues with respect to inspection completeness, technical quality, consistency, attention to health and safety/security, and management review, are chronic and have existed throughout the review period rather than being periodic or limited to portions of the review period. On April 28, 2011, this matter was discussed with the Division Director, who acknowledged the review team's decision to revise its recommendation for this performance indicator.

Based on the IMPEP evaluation criteria, the review team recommended, and the MRB agreed, that North Dakota's performance with respect to the indicator, Technical Quality of Inspections, be found unsatisfactory.

2.4 Technical Quality of Licensing Actions

The review team examined completed casework and interviewed license reviewers for 17 licensing actions covering 13 specific licenses. Licensing actions were reviewed for completeness, consistency, proper radioisotopes and quantities, qualifications of authorized users, adequacy of facilities and equipment, adherence to good health physics practices, financial assurance, security requirements, operating and emergency procedures, appropriateness of license conditions, and overall technical quality. The casework was also reviewed for use of appropriate correspondence, reference to appropriate regulations, supporting documentation, consideration of enforcement history, pre-licensing visits, peer and supervisory review, and proper signatures.

The licensing casework was selected to provide a representative sample of licensing actions completed during the review period. There were 126 licensing actions completed during the review period. Licensing actions selected for evaluation included four new licenses, four renewals, eight amendments, and one license termination. Casework reviewed included a cross-section of license types, including: industrial radiography, radionuclide production (cyclotron), academic broad scope, medical institution-written directive required, fixed gauge, and mobile nuclear medicine. The licensing casework selected also represented licensing actions that were performed by one current license reviewer and three previous license reviewers. A listing of the licensing casework reviewed can be found in Appendix D.

Licensing actions were received by the Branch via mail, fax, or electronic mail. The Branch assigned the licensing action to a reviewer and subsequently updated the status and assignment of the licensing action in the Branch's database. The licensing staff used formal correspondence for technical notices or deficiencies. On some occasions, the staff used electronic mail to follow up with deficiency notices.

The review team identified several licensing actions which had incomplete evaluations of the

health and safety issues and a lack of technical quality. In one case, the Branch issued a license for a complex, highly safety-significant technology without a thorough technical review that conformed with the licensing guidance and ensured health and safety of the workers and the environment. Other case files reviewed indicated instances where licensee's or applicant's operating & emergency procedures did not completely address health and safety issues for unsealed radioactive materials, or which allowed different survey frequencies and different dosimetry calibration ranges than what is allowed by the regulations. In addition, there were two case files reviewed where radiography cameras were authorized for a quantity of radioactive material that exceeded the activity specified in the Sealed Source & Device Registry.

The review also identified several instances where licensing actions for medical use licensees were authorized with incomplete documentation of the training and experience of an Authorized User. These instances included two different physicians who were authorized for 10 CFR 35.200 and 10 CFR 35.400 modalities. In one case, the authorization for the 10 CFR 35.200 modality was granted by the Branch based on a specialty board certification that was not recognized by the NRC. In another case, the authorization for the 10 CFR 35.400 modality was granted by the Branch based on a specialty board certification that was dated prior to the date that the specialty board certification was recognized by the NRC for 10 CFR 35.400. The review team recommends that the State: (1) take measures to ensure that the Branch's review of licensing actions are adequately documented and that licensing actions are thorough and consistent with the regulations and appropriate licensing guidance, and (2) take measures to address the licensing deficiencies that were identified in the comments in Appendix D.

The review team observed that the Branch did not typically review the enforcement history during the license renewal process. Since there has been a significant staff turnover during the review period, the review team expressed to the Branch that license renewals are opportunities for the staff to review the licensee's history and to evaluate the historical licensing and inspection documentation and perform a quality assurance assessment of the license file.

The review team discussed the identified licensing deficiencies with the Branch manager and in part, suggested additional technical licensing training for the staff as an adjunct to any licensing training already received. The Branch manager acknowledged that the types of deficiencies identified would likely be corrected and resolved with additional technical training. The review team recommends that the State provide additional training to the Branch manager and technical staff members regarding technical review of licensing actions, including training to ensure that the staff acquires increased familiarity with: (1) the regulations under North Dakota's equivalent to 10 CFR Parts 30 through 39, and (2) applicable licensing guidance documents for use authorization and license conditions.

The Branch has initiated the process to address maximum possession limits on radioactive materials licenses as requested by Office of Federal and State Materials and Environmental Management Programs (FSME) Letter RCPD-10-007, "Requesting Implementation of a Policy on Maximum Possession Limits for Radioactive Material Licenses" dated June 21, 2010. The Branch was addressing this action as licensees requested amendments or renewals to their licenses.

The review team assessed the Branch's implementation of NRC's pre-licensing guidance issued on September 22, 2008, and transmitted to the Agreement States via FSME Letter RCPD-08-

020, "Requesting Implementation of the Checklist to Provide a Basis for Confidence That Radioactive Material Will Be Used as Specified on a License and the Checklist for Risk-Significant Radioactive Material." Based on the licensing casework reviewed, the Branch had not consistently implemented the essential elements of the pre-licensing guidance under the previous staff members. In the more recent cases that were reviewed, the Branch had performed the pre-licensing visits; however, there was inconsistent documentation of the pre-licensing checklist and pre-licensing visits. The review team recommends that the Branch take measures to determine and document the basis of confidence, through consistent use of the pre-licensing checklist and guidance, that radioactive materials will be used as intended and as described in the application or amendment request, prior to authorizing the material on the license.

Based on the licensing and inspection casework reviewed, the review team identified three licenses that potentially required financial assurance. The Branch had previously identified one of these licenses as requiring financial assurance; however, at the time of the review, the Branch was not able to locate the financial assurance instrument or documentation. The remaining two licenses identified by the review team did not have financial assurance instruments issued. One of the identified licenses did not properly authorize the incidental activated products and therefore financial assurance had not been evaluated by the Branch. The Branch indicated they would review the respective license to evaluate the maximum amount of incidental activated radioactive material for any possible financial assurance requirements. The second license authorized unsealed byproduct material in a quantity amount that would potentially require a decommissioning funding plan. Regarding financial assurance, the review team recommends that the State: (1) develop a procedure or policy to assess financial assurance requirements as part of significant licensing actions and during licensing renewals; (2) review all North Dakota licenses to determine whether licensees require financial assurance, and either request financial assurance for licenses that are authorized to possess the applicable quantities or revise the license conditions to ensure clear quantity limits that will not require provision of financial assurance; and (3) take measures to ensure that any financial assurance instruments received by the Branch are maintained and stored in accordance with State requirements.

The review team verified that the Branch used license conditions to require licensees to follow Increased Controls and Fingerprinting requirements. The review team determined that documents containing sensitive security-related information were appropriately controlled and maintained in a manner to limit access. Specifically, the Branch maintained documents that contained sensitive security-related information in a locked file cabinet; access to the key for the file cabinet was limited to persons who had been granted access by the Branch manager. The review team found that some of the documents that contained sensitive security-related information were marked in a header and footer as containing sensitive information but others had not been marked. This matter was discussed with the Branch manager. Based on this discussion, the review team determined that when the Increased Controls were first issued, the Branch marked all the licenses using appropriate header and footer markings. However, there was no Branch policy or procedure to maintain these markings. As a result, during subsequent licensing actions the headers and footers were inadvertently not retained. When this was further discussed with the Branch manager, the Branch manager immediately developed a written policy and procedure for the technical staff and administrative support staff to follow when processing documents that contain sensitive security-related information. The Branch

manager indicated that the technical staff members and administrative support staff would be briefed on the new policy and procedure. The review team did not identify any instances of improper release of information.

The review team determined that during the latter part of the review period, the Branch had begun to develop licensing templates and follow the NRC NUREG-1556 licensing guidance more diligently. The review team recognized that the current members of the technical staff are still considered in-training for several of the licensing types; however, the licensing actions appeared to be more thorough, complete and consistent. As licensing questions arise, the current technical staff members have been reaching out to NRC for additional guidance in appropriately processing licensing actions. Although many deficiencies were noted in the licensing casework review, the review team did not believe that a finding of unsatisfactory was warranted for this indicator but rather a finding of satisfactory, but needs improvement, was more appropriate for this indicator. The review team's finding was based on several factors, including that the identified deficiencies, other than the radionuclide production (cyclotron) license, indicated examples where health and safety concerns were not fully addressed, rather than a failure to address health and safety concerns. The radionuclide production license did fail to address potentially important health and safety concerns, but this was an isolated example of a unique and complex licensing action, rather than being indicative of a programmatic licensing breakdown. Additionally, the review of licensing casework indicated that licensing deficiencies appeared to be more prevalent in licensing actions completed by former staff members rather than during the latter part of the review period. The current staff members, who have been present during the latter part of the review period, appear to have a more questioning attitude regarding processing licensing actions, leading to better quality license reviews.

Based on the IMPEP evaluation criteria, the review team recommended, and the MRB agreed, that North Dakota's performance with respect to the indicator, Technical Quality of Licensing Actions, be found satisfactory, but needs improvement.

2.5 Technical Quality of Incident and Allegation Activities

In evaluating the effectiveness of the Branch's actions in responding to incidents and allegations, the review team examined the Branch's response to the questionnaire relative to this indicator, evaluated selected incidents reported for North Dakota in the Nuclear Material Events Database (NMED) against those contained in the Branch's files, and evaluated the casework for 9 reported radioactive materials incidents. A listing of the casework examined, with case-specific comments, can be found in Appendix E. The review team also evaluated the Branch's response to 2 allegations that were received by the Branch during the review period. The NRC did not refer any allegations to the Branch during the review period.

The incidents selected for review included incidents related to: damaged equipment, equipment failure, overexposure, contamination, and lost radioactive material. The review team found that when incidents were reported to the Branch by licensees, the Branch in turn reported the events to NRC Headquarters Operations Center as appropriate and in a timely manner. Updates to information regarding reported incidents were found to have been promptly provided by the Branch to the contractor administering the Nuclear Material Events Database (NMED). The review team identified that a few NMED entries for North Dakota events still needed a final

closeout in NMED. This was discussed with the Branch manager so that the events can be closed in NMED as appropriate.

The review team's evaluation of selected incident case files found that the Branch's responses to incidents was often not well coordinated, was inconsistent, and in several cases, not thorough. Based on a review of Branch procedures and discussions with the Branch manager and technical staff, it was revealed that the Branch did not have any formal or informal procedures to respond to radioactive materials incidents. Although the Division has procedures for responding to large-scale events involving radioactive materials, such as a dirty bomb, there were no similar procedures for responding to routine radioactive materials incidents, such as reports of overexposures or equipment failures.

Due to the lack of incident evaluation and response processes or procedures, when the Branch received notification of an incident, there was no consistent approach to perform an initial evaluation of the safety or security significance of an incident to determine the type or level of Branch response. In most cases, on-site inspections or evaluation of incidents were not performed by the Branch and the incidents were instead reviewed in-office through an evaluation of licensee reports. The review team found that the Branch's review of licensee incident reports was inconsistent. In some cases, licensee reports did not contain corrective actions as required by regulation and it did not appear that this was recognized by the Branch so that further information could be obtained from the licensee. In other cases, when corrective actions were described in licensee reports, the Branch's review did not appear to be thorough in that in a few cases it was not recognized by the Branch that the described corrective actions would not be adequate to prevent recurrence of the incident.

For two of the nine incidents examined by the review team, the Branch responded on-site to gather additional information and interview individuals involved in the incident. The review team's evaluation of the case files for the two incidents found that information gathered by the Branch during the on-site visit was not formally documented. The lack of appropriate documentation of the review by the Branch does not provide for knowledge management of the information gathered to facilitate future follow-up. Consequently, on-site reviews did not result in any documented independent review or analysis of the incidents. In both cases, Branch members involved in the on-site incident response were no longer with the Branch at the time of the review and therefore were not available for interview or to provide any formal documentation.

The review team recommends that the State strengthen its incident response program and take measures to ensure that: (1) reported incidents are consistently evaluated to determine the appropriate type and level of Branch response; (2) licensee event reports are reviewed by the Branch for completeness and appropriate corrective actions; and (3) the Branch's evaluation of licensee events, whether based on a review of licensee reports, on-site reviews, or inspection follow-up, is properly documented to facilitate future follow-up.

In evaluating the effectiveness of the Branch's response to allegations, based on a review of Branch procedures and discussions with the Branch manager and technical staff, it was identified that during most of the review period, the Branch did not have a formal procedure to respond to allegations involving licensed activities. Although the Branch had a policy to evaluate allegations on a case-by-case basis, based on the immediate danger to health and

safety, the Branch did not have specific guidance to achieve this. In January 2011, the Branch “adopted” NRC Management Directive 8.8, “Management of Allegations.” Although this NRC Management Directive was adopted by the Branch, it referred to NRC policies, processes, and procedures. The manner in which NRC Management Directive 8.8 was adopted by the State did not provide any practical guidance for Branch implementation (no how-to’s for receipt, processing, and documentation of allegations). Furthermore, NRC Management Directive 8.8 had not been adopted by the State in a manner that would make it consistent with State laws for protecting an alleged’s identity or open records requirements.

The review team discussed the Branch’s actions taken in response to two allegations. The Branch manager indicated that although both allegations involved licensed activity, the concerns were vague, with little specificity, and therefore the Branch was unable to perform any follow-up. Neither concern nor actions taken to address the concern were documented by the Branch. Although NRC did not formally forward any allegations to the Branch during the review period, there was however, an informal concern involving licensed activities that was discussed by the NRC State Agreements Officer with the Branch manager for potential follow-up. In this case, the Branch manager and a member of the technical staff performed some on-site review of the concern and were unable to substantiate the concern. The results of this review were not formally documented although the matter was discussed with the NRC State Agreements Officer.

Due to the lack of Branch-specific processes or procedures for the evaluation of, and response to allegations or concerns, when the Branch received notification of a concern, there was no consistent approach to perform an initial evaluation of the safety or security significance of the concern to determine the type or level of Branch response. Likewise, Branch actions taken in response to concerns were not documented.

The review team recommends that the State strengthen its allegation program and take measures to ensure that: (1) allegations are promptly evaluated to determine the appropriate type and level of Branch response; (2) the Branch’s evaluation of allegations and any actions taken in response to allegations is properly documented to facilitate future follow-up; and (3) processes are in place to provide a response to allegeders as appropriate.

The Branch manager checked with the Department’s legal staff and was informed that there is no State statute that would protect the identity of an allegeder or concerned individual from being disclosed unless confidentiality had been requested in writing and granted. The Branch’s policy, however, is to make all reasonable efforts to protect the identity of allegeders. North Dakota Century Code Article 23-20 provides the specific situations under which confidentiality can be granted.

In reaching a finding for this indicator, the review team considered that the State appropriately notified NRC of reportable events in a timely manner. However, because incident response and allegation procedures were not in place, the State’s performance was marginal in terms of identifying, reviewing, and resolving potential health and safety issues associated with incidents and allegations. The State’s incident response and allegation review activities were often not well coordinated, not complete, not of high technical quality, and sometimes not documented. However, the review team did not believe that the criteria for considering the indicator unsatisfactory were met given that events were properly reported to NRC by the State and the

review team did not identify any situations where the State's performance resulted in the persistence of health and safety problems associated with event response or allegation activities. Taking all of these factors into consideration, the review team believes that a finding of satisfactory, but needs improvement, is more appropriate for this indicator.

Based on the IMPEP evaluation criteria, the review team recommended, and the MRB agreed, that North Dakota's performance with respect to the indicator, Technical Quality of Incident and Allegation Activities, be found satisfactory, but needs improvement.

3.0 NON-COMMON PERFORMANCE INDICATORS

Four non-common performance indicators are used to review Agreement State Programs: (1) Compatibility Requirements, (2) Sealed Source and Device Evaluation Program, (3) Low-level Radioactive Waste Disposal Program, and (4) Uranium Recovery Program. The NRC's Agreement with the State of North Dakota does not relinquish authority to regulate a sealed source and device evaluation program, or a uranium recovery program, so only the first and third non-common performance indicators were applicable to this review.

3.1 Compatibility Requirements

3.1.1 Legislation

North Dakota became an Agreement State on September 1, 1969. Legislative authority to create an agency and enter into an Agreement with NRC is granted in the North Dakota Century Code Chapter 23-20. Century Code Chapter 23-20.1, "Ionizing Radiation Development," designates that the North Dakota Radiation Control Program is administered by the North Dakota Department of Health. The North Dakota Century Code is sufficiently broad to provide authority for the regulation byproduct, source, special nuclear materials, and other radioactive materials.

One rulemaking action affecting the Radiation Control Program was approved during the review period. Prior to the review period, the Radiation Control Program was funded through license fees as well as obtaining approximately 30-40% of its funding from the State's General Fund. During the past year, the proposed rules were adopted that puts in place a 6-year implementation period for the Radiation Control Program to become fully fee funded. This matter went through the State rulemaking process including a public comment period. During the implementation period, licensees will receive a fee increase every year for six years. At the end of six years, the Radiation Control Program will be fully fee funded.

3.1.2 Program Elements Required for Compatibility

The review team examined the Branch's response to the questionnaire, reviewed the status of regulations required to be adopted by the State under the Commission's adequacy and compatibility policy, and verified the adoption of regulations with data obtained from the State Regulation Status Sheet that is maintained by FSME.

North Dakota's regulations for control of radiation are located in the North Dakota Administrative Code, Article 33-10, and apply to all persons who receive, possess, use, transfer, own, or

acquire any source of radiation. North Dakota requires a license for the processing, generation, disposal, use, manufacture, production, acquisition, ownership, receipt, possession, or transfer byproduct, source, certain quantities of special nuclear material, and other radioactive materials occurring naturally or produced artificially or devices or equipment utilizing such materials.

The review team verified that the State's rulemaking process offers the public and other interested parties an opportunity to comment on proposed regulation changes. The rulemaking process begins with the Branch drafting the proposed rules, which are submitted to NRC for a compatibility review. Concurrently, a public notice is then submitted for publication and public comment in the official newspaper of each of the 53 counties in the State. After a public hearing wherein additional comments can be submitted, any received comments will be evaluated and any necessary changes are made. The proposed rules are then submitted to the State Attorney General for a legal opinion. After the Attorney General's legal opinion is received, the legal opinion and rulemaking package are submitted to the State Health Council for adoption. The package is then submitted to the State's Legislative Council. The Legislative Council submits the package to the Legislative Rules Committee for final approval. After final approval is received, the Legislative Council publishes the rules. The rules become effective on the date they are published. The Branch Manager indicated that this rulemaking process typically takes 9-12 months.

After North Dakota regulations are published as final, they are not subject to a sunset review or other administrative reviews.

During the review period, the State significantly revised its radiation control program regulations to provide for NRC regulations to be adopted by reference. The North Dakota regulations were revised to reflect the NRC regulations that were in place on January 1, 2010. The revised regulations became effective on January 1, 2011. Because the North Dakota regulations are "fixed" to NRC's regulations as of January 1, 2010, future revisions or amendments to NRC's regulations will require that North Dakota follow their rulemaking process to revise or amend their regulations.

Current NRC policy requires that Agreement States adopt certain equivalent regulations or legally binding requirements no later than 3 years after the effective date of NRC's regulations. At the time of the review, North Dakota had no overdue regulations and had completed all outstanding regulation changes through the last NRC final rulemaking which was issued in 2009.

Based on the IMPEP evaluation criteria, the review team recommended, and the MRB agreed, that North Dakota's performance with respect to the indicator, Compatibility Requirements, be found satisfactory.

3.2 Low-Level Radioactive Waste (LLRW) Disposal Program

In 1981, NRC amended its Policy Statement, "Criteria for Guidance of States and NRC in Discontinuance of NRC Authority and Assumption Thereof by states Through Agreement," to allow a State to seek an amendment for the regulation of LLRW as a separate category. Those States with existing Agreements prior to 1981 were determined to have continued LLRW disposal authority without the need of an amendment. Although North Dakota has such

authority to regulate a LLRW disposal facility, NRC has not required States to have a program for licensing a disposal facility until such time as the State has been designated as a host State for a LLRW disposal facility. When an Agreement State has been notified or becomes aware of the need to regulate a LLRW disposal facility, it is expected to put in place a regulatory program that will meet the criteria for an adequate and compatibility LLRW program. There are no plans for a commercial LLRW disposal facility in North Dakota. Accordingly, the review team did not review this indicator.

4.0 SUMMARY

As noted in Sections 2.0 and 3.0 above, the review team recommends that North Dakota's performance be found unsatisfactory for the performance indicator Technical Quality of Inspections, and satisfactory, but needs improvement, for the performance indicators: Status of the Materials Inspection Program, Technical Quality of Licensing Actions, and Technical Quality of Incident and Allegation Activities. The review team found North Dakota's performance to be satisfactory for the other indicators reviewed. The review team made 11 recommendations regarding the performance of the State. Overall, the review team recommended, and the MRB agreed, that the North Dakota Agreement State Program be found adequate, but needs improvement, to protect public health and safety, and compatible with NRC's program.

Based on the results of the current IMPEP review, and in accordance with the criteria in NRC Management Directive 5.6, the review team recommended, and the MRB agreed, that a period of Heightened Oversight be initiated for North Dakota. Heightened Oversight may be used in cases where one or more performance indicators are found unsatisfactory. Heightened Oversight is a formal process that allows the NRC to maintain an increased level of communication with an Agreement State program. The review team believes that Heightened Oversight will be a useful tool in assessing the State's progress toward addressing the programmatic issues and deficiencies identified during the review.

The review team further recommended, and the MRB agreed, that a Periodic Meeting be held within 1 year to assess the State's progress in addressing the open recommendations, and that a follow-up IMPEP review take place approximately 1 year following the Periodic Meeting (2 years from current IMPEP). The review team believes that the performance of a follow-up IMPEP at approximately 2 years from the current IMPEP will allow the State sufficient time to correct programmatic issues identified during the review. However, the follow-up IMPEP should be coordinated with the State to provide for the date of the follow-up IMPEP to be offset from the State's biennial legislative cycle.

Below are the review team's recommendations, as mentioned in the report, for evaluation and implementation by the State:

1. The review team recommends that the State: (1) update its existing procedures and develop new procedures, as necessary, to memorialize the policies and practices of the Agreement State program and to serve as a knowledge management tool, and (2) examine options to increase staff retention and/or develop sufficient depth in staffing to effectively implement the program. (Section 2.1)
2. The review team recommends that the State take measures to ensure that initial

inspections are performed at the interval prescribed in IMC 2800. (Section 2.2)

3. The review team recommends that the State take measures to ensure that inspection findings are communicated to licensees within 30 days of the date of the inspection. (Section 2.2)
4. The review team recommends that the State: (1) take measures to ensure that sufficient information pertaining to inspection observations and identified non-compliances is documented in inspection records and in letters to licensees and that these documents be appropriately reviewed by management, prior to issuance, for thoroughness and consistency, and (2) develop and implement a plan to address comments noted in Appendix C related to identified items of non-compliance that were not included in findings that were dispatched to licensees. (Section 2.3)
5. The review team recommends that the State obtain additional training (formal and on-the-job, as appropriate) for the Branch manager and members of the technical staff to enhance inspection skills, particularly with regards to: (1) radiation safety issues associated with cyclotron operations, and (2) proper operation and use of radiation survey and measurement instrumentation. (Section 2.3)
6. The review team recommends that the State: (1) take measures to ensure that the Branch's review of licensing actions are adequately documented and that licensing actions are thorough and consistent with the regulations and appropriate licensing guidance, and (2) take measures to address the licensing deficiencies that were identified in the comments in Appendix D. (Section 2.4)
7. The review team recommends that the State provide additional training to the Branch manager and technical staff members regarding technical review of licensing actions, including training to ensure that the staff acquires increased familiarity with: (1) the regulations under North Dakota's equivalent to 10 CFR Parts 30 through 39, and (2) applicable licensing guidance documents for use authorization and license conditions. (Section 2.4)
8. The review team recommends that the Branch take measures to determine and document the basis of confidence, through consistent use of the pre-licensing checklist and guidance, that radioactive materials will be used as intended and as described in the application or amendment request, prior to authorizing the material on the license. (Section 2.4)
9. Regarding financial assurance, the review team recommends that the State: (1) develop a procedure or policy to assess finance assurance requirements as part of significant licensing actions and during licensing renewals; (2) review all North Dakota licenses to determine whether licensees require financial assurance, and either request financial assurance for licenses that are authorized to possess the applicable quantities or revise the license conditions to ensure clear quantity limits that will not require provision of financial assurance; and (3) take measures to ensure that any financial assurance instruments received by the Branch are maintained and stored in accordance with State requirements. (Section 2.4)

10. The review team recommends that the State strengthen its incident response program and take measures to ensure that: (1) reported incidents are consistently evaluated to determine the appropriate type and level of Branch response; (2) licensee event reports are reviewed by the Branch for completeness and appropriate corrective actions; and (3) the Branch's evaluation of licensee events, whether based on a review of licensee reports, on-site reviews, or inspection follow-up, is properly documented to facilitate future follow-up. (Section 2.5)

11. The review team recommends that the State strengthen its allegation program and take measures to ensure that: (1) allegations are promptly evaluated to determine the appropriate type and level of Branch response; (2) the Branch's evaluation of allegations and any actions taken in response to allegations is properly documented to facilitate future follow-up; and (3) processes are in place to provide a response to alлегers as appropriate. (Section 2.5)

LIST OF APPENDICES

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Appendix D	License Casework Reviews
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APPENDIX A

IMPEP REVIEW TEAM MEMBERS

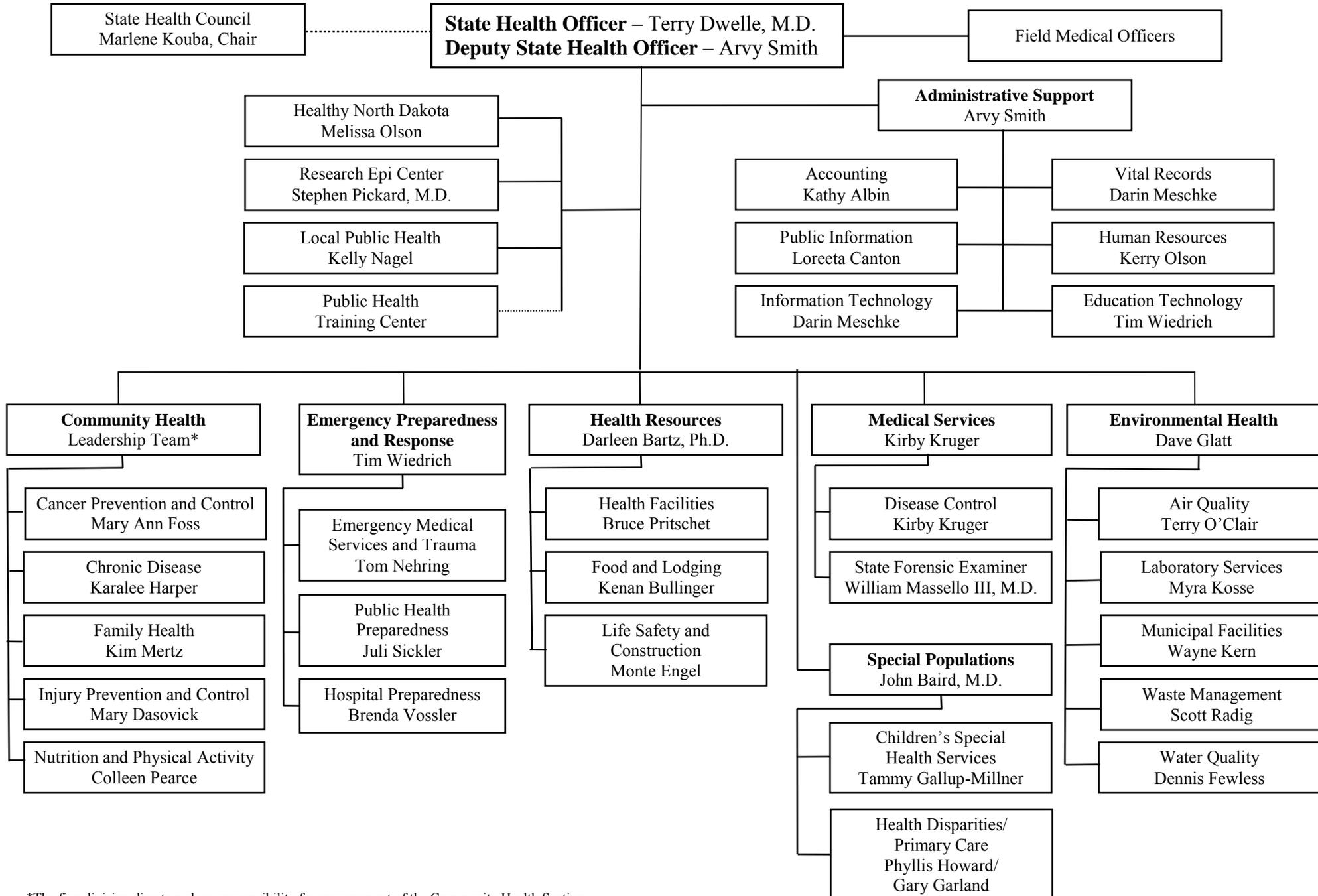
Name	Area of Responsibility
Janine Katanic, FSME	Team Leader Technical Staffing and Training Inspector Accompaniments Technical Quality of Incident and Allegation Activities Compatibility Requirements
Rachel Browder, Region IV	Technical Quality of Licensing Actions
Michele Greenwell, Kentucky	Status of Materials Inspection Program Technical Quality of Inspections

APPENDIX B

NORTH DAKOTA ORGANIZATION CHARTS

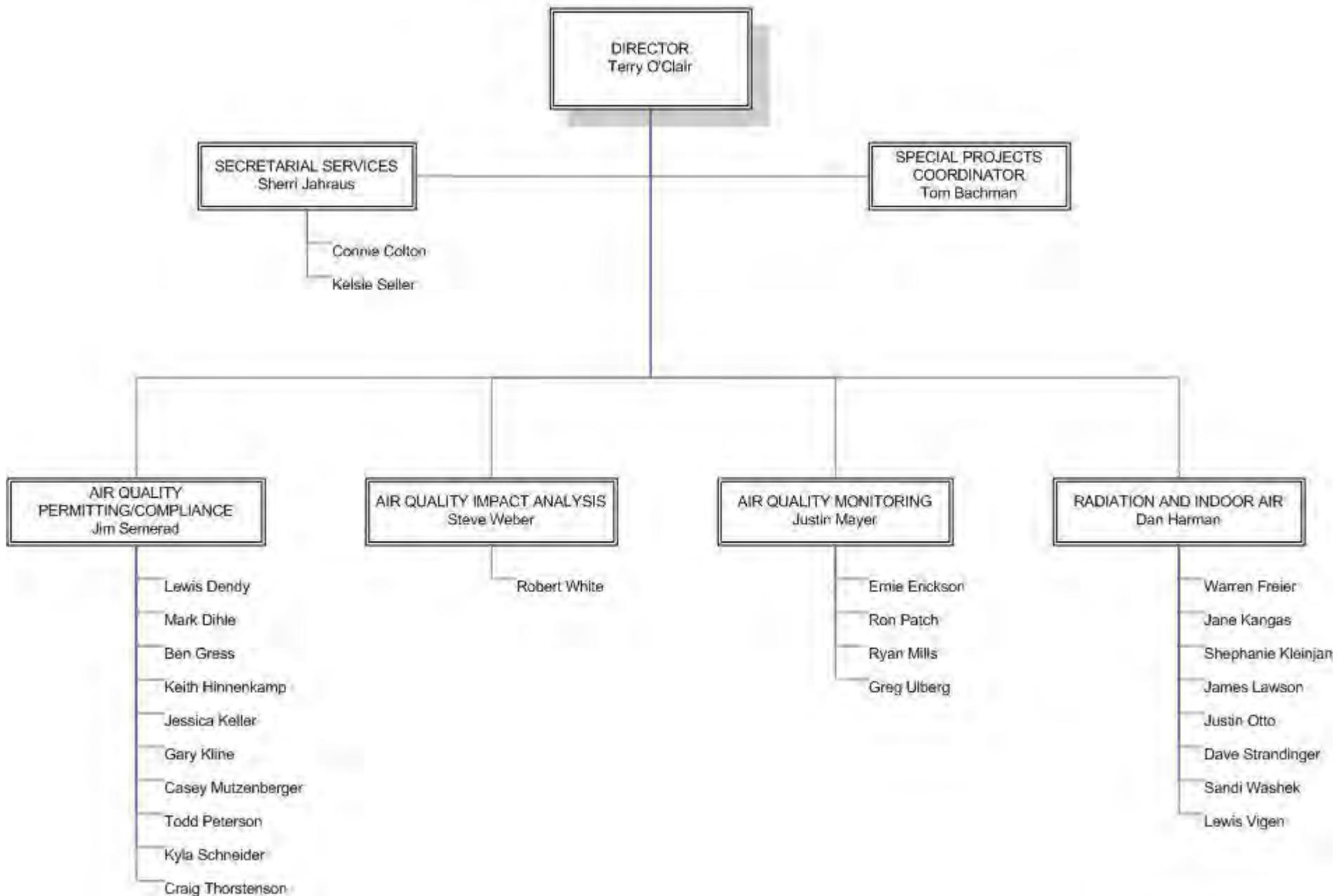
ADAMS ACCESSION NO.: ML110810045

FIGURE 1
North Dakota Department of Health
Organizational Chart
 November 2010



*The five division directors share responsibility for management of the Community Health Section.

FIGURE 2
 NORTH DAKOTA DEPARTMENT OF HEALTH
 DIVISION OF AIR QUALITY



APPENDIX C

INSPECTION CASEWORK REVIEWS

NOTE: CASEWORK LISTED WITHOUT COMMENT IS INCLUDED FOR COMPLETENESS ONLY.

File No.: 1

Licensee: Bismarck Cancer Center
Inspection Type: Routine, Unannounced
Inspection Date: 10/8/09

License No.: 33-41919-01
Priority: 2
Inspector: LR

File No.: 2

Licensee: Medcenter One Health System
Inspection Type: Routine, Announced
Inspection Date: 1/29/08

License No.: 33-00043-05
Priority: 3
Inspectors: LR, CS

Comment:

The documented inspection record identified an apparent non-compliance item that was not included in the inspection findings that were dispatched to the licensee.

File No.: 3

Licensee: Medcenter One Health System
Inspection Type: Routine, Announced
Inspection Date: 1/27-28/11

License No.: 33-00043-05
Priority: 3
Inspectors: DH, DS

Comment:

The inspection findings were dispatched to the licensee approximately 40 days after the inspection date.

File No.: 4

Licensee: DMS Imaging
Inspection Type: Routine, Announced
Inspection Date: 12/8/10

License No.: 33-11325-01
Priority: 3
Inspectors: DS, LR

File No.: 5

Licensee: University of North Dakota
Inspection Type: Initial, Announced
Inspection Date: 1/31-2/1/11

License No.: 33-48922-01
Priority: 2
Inspectors: DS, DH

Comments:

- a) Using a previous version of IMC 2800, the Branch had identified this as a Priority 5 inspection. Based on the Branch's adoption of the revised IMC 2800, the Branch revised the inspection priority to Priority 2.
- b) Some health and safety issues identified during the inspection were not documented in the inspection findings issued to the licensee.
- c) The inspection findings, which addressed significant health and safety issues, were issued 38 days after the date of the inspection.

File No.: 6

Licensee: Sanford Medical Center-Fargo
Inspection Type: Routine, Announced
Inspection Date: 6/18/09

License No.: 33-10227-02
Priority: 2
Inspectors: LR, DH

Comments:

- a) The inspection report did not document if a review was performed related to items of non-compliance that were identified during the previous inspection.
- b) The inspection findings were dispatched to the licensee over 90 days after the date of the inspection.

File No.: 7

Licensee: Sanford Medical Center-Fargo
Inspection Type: Routine, Announced
Inspection Date: 2/2/11

License No.: 33-10227-02
Priority: 2
Inspectors: DS, DH

Comment: The inspection record did not document a review of the licensee's compliance related to procedures requiring written directives.

File No.: 8

Licensee: University of North Dakota
Inspection Type: Routine, Special, Announced
Inspection Date: 2/1/08

License No.: 33-12827-01
Priority: 3
Inspectors: CS, LR

Comments:

- a) The inspection record did not document if a review was performed related to items of non-compliance that were identified during the previous inspection.
- b) An inspector from the State of Minnesota participated in this inspection.

File No.: 9

Licensee: University of North Dakota
Inspection Type: Routine, Announced
Inspection Date: 1/31-2/1/11

License No.: 33-12827-01
Priority: 3
Inspectors: DH, DS

Comment:

The database indicated that the inspection findings were dispatched to the licensee 38 days after the date of the inspection. However, the dispatched inspection record could not be located for review.

File No.: 10

Licensee: Braun Intertec Corporation
Inspection Type: Initial, Special, Announced
Inspection Date: 2/3/11

License No.: 33-48303-01
Priority: 1
Inspectors: DS, DH

File No.: 11

Licensee: Midwest Industrial X-Ray
Inspection Type: Routine, Special, Announced
Inspection Date: 11/17/10

License No.: 33-14907-01
Priority: 1
Inspectors: DS, DH

File No.: 12

Licensee: Weatherford International, LTD
Inspection Type: Initial, Announced
Inspection Date: 2/2/10

License No.: 33-46901-01
Priority: 3
Inspectors: DS, LR

File No.: 13

Licensee: Trinity Health
Inspection Type: Routine, Announced
Inspection Date: 1/28/10

License No.: 33-04608-01
Priority: 2
Inspectors: LR

INSPECTOR ACCOMPANIMENTS

The following inspector accompaniments were performed prior to the on-site IMPEP review:

Accompaniment No.: 1

Licensee: University of North Dakota
Inspection Type: Initial, Announced
Inspection Date: 1/31-2/1/11

License No.: 33-48922-01
Priority: 2
Inspector: DH, DS

Comments:

- a) The inspector did not have familiarity with the licensed cyclotron operations or with radiation safety and health physics issues associated with cyclotron operations. As a result, the inspector did not identify several apparent health physics and radiation safety issues associated with these risk-significant operations.
- b) The inspection was unable to be completed and as a result, certain higher risk significance activities were not reviewed. A follow-up inspection was scheduled to be performed within approximately 6 months.
- c) The inspector did not have a thorough understanding of the proper use and operation of radiation detection and survey instrumentation.

Accompaniment No.: 2

Licensee: University of North Dakota
Inspection Type: Routine, Announced
Inspection Date: 1/31-2/1/11

License No.: 33-12827-01
Priority: 3
Inspector: DH, DS

Comments:

- a) The inspection was unable to be completed and as a result, certain higher risk significance activities were not reviewed. A follow-up inspection was scheduled to be performed within approximately 6 months.

- b) Issues regarding licensed activities that were raised during the inspector's performance observations were not adequately followed up by the inspector.
- c) The inspector did not review the licensee's corrective actions related to a previously identified non-compliance.

Accompaniment No.: 3

Licensee: Sanford Medical Center - Fargo

Inspection Type: Routine, Announced

Inspection Date: 2/2/11

License No.: 33-10227-02

Priority: 3

Inspector: DS, DH

Comments:

- a) The inspector did not identify an issue related to the security of unattended radioactive materials.
- b) The inspector did not adequately review licensee compliance related to various therapeutic modalities requiring written directives.
- c) The inspector did not have a thorough understanding of the proper use and operation of radiation survey instrumentation.

Accompaniment No.: 4

Licensee: Braun Intertec Corporation

Inspection Type: Special, Initial, Announced

Inspection Date: 2/3/11

License No.: 33-48303-01

Priority: 1

Inspector: DS, DH

Comments:

- a) The inspector did not perform a thorough initial inspection in that it only addressed issues related to security requirements and did not address the licensee's radiation safety program related to radiographic operations. The inspector was unable to describe what plans, if any, were being made to inspect the remainder of the licensee's program.
- b) An initial inspection of licensee implementation of security requirements warranted a more detailed review than what was performed by the inspector. The inspector did not have a thorough understanding of the security requirements, leading to confusion regarding the adequacy of licensee compliance.

Accompaniment No.: 5

Licensee: North Dakota State University

Inspection Type: Special, Announced

Inspection Date: 3/14-16/11

License No.: 33-06769-06

Priority: 3

Inspector: DH, DS

Comments:

- a) The inspector did not adequately review several apparent security-related issues. The inspector did not identify or did not understand the security significance of a non-compliance related to security requirements and therefore did not promptly notify the licensee of the need to take immediate corrective actions. The inspector did not have a thorough understanding of the security requirements and could not clearly explain to the licensee what actions were necessary to achieve compliance.
- b) The inspector did not have a thorough understanding of the proper use and

- operation of radiation survey instrumentation.
- c) The inspector did not identify evidence of the consumption of food and the storage of personal medication in areas where radioactive materials were used or stored so that these issues could be promptly corrected.
 - d) The inspector did not identify an issue involving the storage of portable gauges.

Accompaniment No.: 6

Licensee: Innovis Health, LLC

Inspection Type: Routine, Announced

Inspection Date: 3/16-17/11

License No.: 33-02604-01

Priority: 3

Inspector: DS, DH

Comment:

The inspector did not have a thorough understanding of the proper use and operation of radiation survey instrumentation.

APPENDIX D

LICENSE CASEWORK REVIEWS

NOTE: CASEWORK LISTED WITHOUT COMMENT IS INCLUDED FOR COMPLETENESS ONLY.

File No.: 1

Licensee: Institute of Diagnostic Imaging

Type of Action: Termination

Date Issued: 2/22/11

License No.: 33-39805-01

Previous Amendment No.: 05

License Reviewer: DS

File No.: 2

Licensee: University of North Dakota

Type of Action: New

Date Issued: 9/22/10

License No.: 33-48922-01

Amendment No.: New

License Reviewer: DS

Comments:

- a) This license was split from the University of North Dakota Broad Scope license and therefore some of the tie-downs were still contained under the Broad Scope license and should have been resubmitted for this cyclotron license.
- b) The license reviewer did not request the activated products for the cyclotron model from the licensee and therefore did not authorize the material on the license.
- c) The license reviewer did not calculate financial assurance for the activated products.
- d) The design/drawings, including the conduits and tubing of the material transfer, were not included as part of the submittal.
- e) The detailed health and safety elements as described in NUREG-1556, Volume 21, were not submitted as part of the application, including: radioactive waste, ventilation, contamination controls, packaging and transportation.

File No.: 3

Licensee: University of North Dakota

Type of Action: Renewal

Date Issued: 9/29/10

License No.: 33-12827-01

Amendment No.: 32

License Reviewer: DS

Comments:

- a) The license reviewer did not ensure that the broad scope licensee submitted adequate procedures for approval of users and facilities that gave the Branch a basis of confidence that the authorizations would be protective of health and safety of the public and environment.
- b) The license reviewer did not ensure that special radiation safety protocols were in place for handling unsealed radioactive material such as P-32.
- c) The license reviewer did not ensure that adequate instrument calibration procedures and the individual's training and experience for who would be performing the calibration was included in the license application. If instrument calibration activity was performed as a service to other licensees, this activity should be authorized as a service activity.

File No.: 4

Licensee: DMS Health Technologies
Type of Action: Amendment
Date Issued: 9/20/10

License No.: 33-11325-01
Amendment No.: 52
License Reviewer: DS

File No.: 5

Licensee: DMS Health Technologies
Type of Action: Renewal
Date Issued: 2/25/09

License No.: 33-11325-01
Amendment No.: 51
License Reviewer: LR

File No.: 6

Licensee: Medcenter One Health Systems
Type of Action: Amendment
Date Issued: 4/17/09

License No.: 33-00043-01
Amendment No.: 54
License Reviewer: JR

Comment:

The license reviewer authorized an individual on the license who was not qualified for the 10 CFR 35.200 modality under the regulations.

File No.: 7

Licensee: Medcenter One Health Systems
Type of Action: Amendment
Date Issued: 11/5/10

License No.: 33-00043-05
Amendment No.: 58
License Reviewer: LR

File No.: 8

Licensee: Braun Intertec Corporation
Type of Action: New
Date Issued: 3/4/10

License No.: 33-48303-01
Amendment No.: New
License Reviewer: JR

Comment:

The license reviewer incorrectly authorized a radiography camera with greater activity than what is authorized under the Sealed Source & Device Registry.

File No.: 9

Licensee: St. Alexis Medical Center
Type of Action: Amendment
Date Issued: 6/9/09

License No.: 33-11320-01
Amendment No.: 39
License Reviewer: LR

Comment:

The license reviewer authorized an individual on the license who was not qualified for the 10 CFR 35.400 modality under the regulations.

File No.: 10

Licensee: Medcenter One Health System
Type of Action: Amendment
Date Issued: 8/10/07

License No.: 33-00043-05
Amendment No.: 49
License Reviewer: CS

File No.: 11

Licensee: Midwest Industrial X-Ray, Inc.
Type of Action: Amendment
Date Issued: 11/30/10

License No.: 33-14907-01
Amendment No.: 18
License Reviewer: DS

File No.: 12

Licensee: Midwest Industrial X-Ray, Inc.
Type of Action: Renewal
Date Issued: 8/29/08

License No.: 33-14907-01
Amendment No.: 16
License Reviewer: LR

Comments:

- a) The license reviewer incorrectly authorized a radiography camera with greater activity than what is authorized under the Sealed Source & Device Registry.
- b) The license reviewer approved a permanent radiography facility without adequate drawings, dose rates, and roof access information.
- c) The license reviewer incorrectly authorized Operating & Emergency procedures which granted the pocket dosimeter range to exceed the range provided in the regulations and granted the alarming ratemeter accuracy range to exceed the range provided in the regulations.

File No.: 13

Licensee: Minot State University
Type of Action: New
Date Issued: 1/9/09

License No.: 33-45808-01
Amendment No.: New
License Reviewer: LR

Comment:

- a) The license reviewer did not complete the Pre-Licensing checklist.
- b) The license reviewer did not ensure that special radiation safety protocols were in place for handling unsealed radioactive material such as P-32.

File No.: 14

Licensee: Weatherford International, Inc.
Type of Action: New
Date Issued: 12/2/08

License No.: 33-46901-01
Amendment No.: New
License Reviewer: JR

File No.: 15

Licensee: Schlumberger Technology
Type of Action: Amendment
Date Issued: 6/14/08

License No.: 33-10108-01
Amendment No.: 22
License Reviewer: CS

File No.: 16

Licensee: Midwest Radiation Physicists, Inc.
Type of Action: Renewal
Date Issued: 5/17/10

License No.: 33-09908-01
Amendment No.: 13
License Reviewer: DS

File No.: 17

Licensee: Sanford Medical Center - Fargo

Type of Action: Amendment

Date Issued: 9/13/10

License No.: 33-10227-02

Amendment No.: 51

License Reviewer: DS

Comment:

- a) The license reviewer did not authorize a medical physicist for decay correction of the Sr-90 eye plaque, as required by the regulations.
- b) While most of the line-listed radionuclides had sealed source model numbers authorized on the license, there was one radionuclide that did not specify the sealed source model number(s).

APPENDIX E

INCIDENT CASEWORK REVIEWS

NOTE: CASEWORK LISTED WITHOUT COMMENT IS INCLUDED FOR COMPLETENESS ONLY.

File No.: 1

Licensee: Northern Technologies, Inc.

Date of Incident: 10/21/10

Investigation Date: 10/21/10

License No.: 33-32112-01

NMED No.: 100526

Type of Incident: Damage to Equipment

Type of Investigation: Licensee Report

File No.: 2

Licensee: Weatherford International, Inc.

Date of Incident: 5/21/10

Investigation Date: 5/21/10

License No.: 33-46901-01

NMED No.: 100270

Type of Incident: Overexposure

Type of Investigation: Licensee Report

Comment:

The licensee's final report providing their final dosimetry analysis and corrective actions was not in the case file during the review and had to be requested from the licensee by the Branch manager.

File No.: 3

Licensee: T&K Inspection, Inc.

Date of Incident: 5/10/10

Investigation Date: 5/10/10

License No.: 33-22313-01

NMED No.: 100251

Type of Incident: Equipment Failure/Overexposure

Type of Investigation: Licensee Report

File No.: 4

Licensee: Team Industrial Services, Inc.

Date of Incident: 5/18/09

Investigation Date: 5/18/09

License No.: 42-32219-01

NMED No.: 090504

Type of Incident: Damage to Equipment/Equipment Failure

Type of Investigation: Licensee Report, Site Visit

Comments:

- a) The licensee was operating under reciprocity in North Dakota.
- b) Two members of the technical staff performed a site visit. However, information gathered during the site visit was not formally documented. The case file only contained hand-written "scratch" notes from the technical staff which were hard to decipher and provided no documentation of an independent review or analysis of the incident.

File No.: 5

Licensee: Midwest Industrial X-Ray, Inc.

Date of Incident: 7/8/08

Investigation Date: 7/8/08

License No.: 33-14907-01

NMED No.: 080382

Type of Incident: Equipment Failure/Overexposure

Type of Investigation: Licensee Report, Site Visit

Comments:

- a) The licensee's final report providing their corrective actions, as required by regulation, could not be located in the case file.
- b) The Branch manager and a member of the technical staff performed a site visit. However, information gathered during the site visit was not formally documented. The case file only contained hand-written "scratch" notes from the technical staff which were hard to decipher and provided no documentation of an independent review or analysis of the incident.

File No.: 6

Licensee: Dakota Gasification Company

Date of Incident: 2/16/10

Investigation Date: 2/16/10

License No.: 33-15327-01

NMED No.: 100088

Type of Incident: Equipment Failure

Type of Investigation: Licensee Report/Email

File No.: 7

Licensee: Sanjel Corporation

Date of Incident: 3/13/11

Investigation Date: 3/13/11

License No.: 33-42824-01

NMED No.: 110136

Type of Incident: Damage to Equipment and Facility

Type of Investigation: Licensee Report/Telephone

Comment:

The State is awaiting final disposition of the damaged equipment before closing the incident case file.

File No.: 8

Licensee: University of North Dakota

Date of Incident: 10/15-11/14/07

Investigation Date: 12/10/07

License No.: 33-12827-01

NMED No.: 070754

Type of Incident: Overexposure/Contamination Event

Type of Investigation: Licensee Report

Comments:

- a) The contamination event occurred during the period from 10/15-11/14/07 and was reported to the State on 12/10/07.
- b) The dosimetry analysis indicated that the incident was not a true overexposure but rather the result of a contaminated dosimeter. The State did not identify that the licensee's report did not address any probable causal factors or corrective actions related to the contamination event.

File No.: 9

Licensee: Wal-Mart

Date of Incident: 1/8/09

Investigation Date: 1/8/09

License No.: General License

NMED No.: 090060

Type of Incident: Loss of Radioactive Material

Type of Investigation: Licensee Report

ATTACHMENT

May 31, 2011 Letter from Daniel E. Harman
North Dakota Response to the Draft Report
ADAMS Accession No.: ML111511081

June 13, 2011 Letter from Daniel E. Harman
North Dakota Revised Response to the Draft Report
ADAMS Accession No.: ML111660475

NRC Comment Resolution to May 31, 2011 Letter
ADAMS Accession No.: ML111580527

Included in this response to the *Integrated Materials Performance Evaluation Program, Review of the North Dakota Agreement State Program* (ML111220487) are three technical corrections to the draft report and actions taken to address each of the recommendations.

The first technical correction is in Section 2.1, paragraph 4, third line from the bottom. Please change "... inspection of a radionuclide production (cyclotron) facility." to read "... inspection of an Academic Type A Broad Scope with an associated medical facility."

The second technical correction is in Section 3.1, subsection 3.1.1, second paragraph which should read as follows:

One rulemaking action affecting the Radiation Control Program was approved during the review period. Prior to the review period, the Radiation Control Program was funded through license fees as well as obtaining approximately 30-40% of its funding from the State's General Fund. During the past year, the proposed rules were adopted that puts in place a 6-year implementation period for the Radiation Control Program to become fully fee funded. This matter went through the State's rulemaking process including a public comment period. During the implementation period, licensees will receive a fee increase every year for six years. At the end of six years, the Radiation Control Program will be fully fee funded.

The third technical correction is in Section 3.1, subsection 3.1.3, third paragraph which should read as follows:

The review team verified that the State's rulemaking process offers the public and other interested parties an opportunity to comment on proposed regulation changes. The rulemaking process begins with the Branch drafting the proposed rules, which are submitted to NRC for a compatibility review. Concurrently, a public notice is then submitted for publication and public comment in the official newspaper of each of the 53 counties in the State. After a public hearing wherein additional comments can be submitted, any received comments will be evaluated and any necessary changes are made. The proposed rules are then submitted to the State Attorney General for a legal opinion. After the Attorney General's legal opinion is received, the legal opinion and rulemaking package are submitted to the State Health Council for adoption. The package is then submitted to the State's Legislative Council. The Legislative Council submits the package to the Legislative Rules Committee for final approval. After final approval is received, the Legislative Council publishes the rules. The rules become effective on the date they are published. The Branch Manager indicated that this rulemaking process typically takes 9-12 months.

Below are review team's recommendations, as mentioned in the report, for evaluation and implementation. Following each recommendation are the actions implemented with training or actions planned.

1. The review team recommends that the State update its existing procedures and develop new procedures, as necessary, to memorialize the policies and practices of the Agreement State program and to serve as a knowledge management tool. (Section 2.1)
 - a. After considering several options, the *Radiation Control Program Administrative Procedures Manual* (Manual) was selected as the repository for memorializing all policies and procedures. In the instance of, for example, inspection procedures, the Manual will simply contain a reference to the Radiation Control Program's *Materials Inspection Manual*. In other instances, the policy or procedure will be incorporated into the Manual.
2. The review team recommends that the State take measures to ensure that initial inspections are performed at the interval prescribed in IMC 2800. (Section 2.2)
 - a. This recommendation was addressed by adding to the pre-licensing inspection form a step that sets the initial inspection due date to nine months after the license is issued. The immediate fix for handling this in the database is as follows: The "Inspection Priority" will be set to "1" and the "Inspection Date" will be set to the license "Effective Date" plus nine (9) months. After the initial inspection, the "Inspection Priority" will be reset to the appropriate priority for the NRC Program Code. A permanent fix will be made with the next database update.
3. The review team recommends that the State take measures to ensure that inspection findings are communicated to licensees within 30 days of the date of the inspection. (Section 2.2)
 - a. Bi-weekly Radioactive Materials staff meetings are held on Monday morning to review the status of active inspection reports. These meetings are scheduled using MS Outlook Calendar. If a Monday is a holiday, then the meeting is held on Tuesday. If the Manager is unavailable, the lead HP convenes the meeting. This will be documented in the Manual with the next update.
4. The review team recommends that the State take measures to ensure that sufficient information pertaining to inspection observations and identified non-compliances is documented in inspection records and in letters to licensees and that these documents be appropriately reviewed by management, prior to issuance, for thoroughness and consistency. (Section 2.3)
 - a. Arrangements have been made with NRC Region IV to accompany and observe Region IV inspectors when they are in South Dakota, Wyoming and Montana. Learning from NRC inspectors and applying what is learned as well as passing that training on to the other two staff inspectors is expected to improve our inspections to a "Satisfactory" level within two years.
5. The review team recommends that the State obtain additional training (formal and on- the-job, as appropriate) for the Branch manager and members of the technical staff to enhance inspection skills, particularly with regards to: (1) radiation safety issues associated with cyclotron operations, and (2) proper operation and use of radiation survey and measurement instrumentation. (Section 2.3)

- a. Arrangements have been made with the Minnesota program to inspect the UND cyclotron while we observe their inspection technique and procedure. Also, we have arranged to visit a same-brand, similar configuration, cyclotron in Minnesota at their convenience.
 - b. Arrangements have been made with NRC Region IV to accompany their inspectors when they are in South Dakota, Wyoming and Montana. To date NRC has provided opportunities to accompany inspections in both Wyoming and South Dakota. We have had to pass on both opportunities because we were unable make the arrangements due to flood related activities in the Bismarck-Mandan area. We hope to still make arrangements to accompany NRC inspectors.
 - c. For training in proper operation and use of radiation survey and measurement instrumentation, the applicable sections in ORAU's Applied Health Physics training course, Books 1 and 2 will be used for classroom instruction. Laboratory type exercises will be drawn from the Lab Workbook exercises. The training will be documented in the individual Radiation Control Program - Training Regimen Checklist.
6. The review team recommends that the State take measures to ensure that the Branch's review of licensing actions are adequately documented and that licensing actions are thorough and consistent with the regulations and appropriate licensing guidance. (Section 2.4)
 - a. A request has been made to Region IV through our State Agreement Officer, Rachael Browder, to have an NRC licensing person come to North Dakota to review our process, practices, and license templates for improvements. We will select two or three of the more challenging licenses to review for accuracy and completeness. The final process and procedures will be documented in the Manual.
7. The review team recommends that the State provide additional training to the Branch manager and technical staff members regarding technical review of licensing actions, including training to ensure that the staff acquires increased familiarity with: (1) the regulations under North Dakota's equivalent to 10 CFR Parts 30 through 39, and (2) applicable licensing guidance documents for use authorization and license conditions. (Section 2.4)
 - a. On January 1, 2011, the applicable NRC rules were adopted by reference. Therefore, the format is new, the location of some rules are new, and some rule content has changed since the last rule update of the 2002 NRC rules. With time and experience, knowledge of the new rules will be gained.
 - b. We have obtained copies of applicable license templates and standard conditions from Region IV Licensing Branch. We plan to have someone from the Licensing Branch come here to help us work through the licensing process using the process NRC uses.
8. The review team recommends that the Branch take measures to determine and document the basis of confidence, through consistent use of the pre-licensing checklist and guidance, that radioactive materials will be used as intended and as described in the

application or amendment request, prior to authorizing the material on the license. (Section 2.4)

- a. The Pre-licensing Checklist and Implementing Guidance check list issues by NRC on September 22, 2008 has been fully implemented. The check lists, along with the instructions, have been provided to the staff and reviewed during a biweekly program staff meeting. This change to the licensing process will be incorporated in the Manual with the next update.
9. Regarding financial assurance, the review team recommends that the State: (1) develop a procedure or policy to assess finance assurance requirements as part of significant licensing actions and during licensing renewals; (2) review all North Dakota licenses to determine whether licensees require financial assurance, and either request financial assurance for licenses that are authorized to possess the applicable quantities or revise the license conditions to ensure clear quantity limits that will not require provision of financial assurance; and (3) take measures to ensure that any financial assurance instruments received by the Branch are maintained and stored in accordance with State requirements. (Section 2.4)
- a. The review for financial assurance has been added to initial license application and any licensing action that adds an isotope or increases the licensed activity. If the license already requires financial assurance, then any isotope change will be reviewed to determine if the action changes the required financial assurance. If any licensing action changes the licensee's financial assurance status, a specific letter will be sent to the licensee addressing the status change. This will be documented in the Manual with the next update.
 - b. Beginning June 1, we will perform the financial assurance calculations during updating the licenses to include maximum activity per source and maximum possession activity per isotope. Performing the calculations on licenses already updated will be completed no later than December 2011.
 - c. A tracking spreadsheet has been created using templates provided by NRC. The existing financial assurance documents have been logged in and stored in a lock fireproof file cabinet.
10. The review team recommends that the State strengthen its incident response program and take measures to ensure that: (1) reported incidents are consistently evaluated to determine the appropriate type and level of Branch response; (2) licensee event reports are reviewed by the Branch for completeness and appropriate corrective actions; and (3) the Branch's evaluation of licensee events, whether based on a review of licensee reports, on-site reviews, or inspection follow-up, is properly documented to facilitate future follow-up. (Section 2.5)
- a. The Program has acquired the NRC's *Handling of Materials Licensee Event Reports (LERs) by DNMS Staff* (PG9007B.1) to use as a template for handling reported events.
 - b. A full review of how to best use and incorporate this document into our program has not been completed. Once a resolution is reached, training will be provided and documented in the Manual.
11. The review team recommends that the State strengthen its allegation program and take measures to ensure that: (1) allegations are promptly evaluated to determine the appropriate type and level of Branch response; (2) the Branch's evaluation of

allegations and any actions taken in response to allegations is properly documented to facilitate future follow-up; and (3) processes are in place to provide a response to allegeders as appropriate. (Section 2.5)

- a. The plan is to use NRC's DH 8.8 (Management of Allegations) along with NRC's *Allegation Receipt Form* and *Branch Evaluation, Plan & Recommendation* form as the foundation for handling allegations. Once the process and procedure is completed, training will be provided and the process and procedure documented in the Manual.

REVISED North Dakota Response to 2011 IMPEP Recommendations

June 13, 2011

Below are review team's recommendations, as mentioned in the report, for evaluation and implementation. Following each recommendation are the actions implemented or planned with the training or actions planned.

1. The review team recommends that the State update its existing procedures and develop new procedures, as necessary, to memorialize the policies and practices of the Agreement State program and to serve as a knowledge management tool. (Section 2.1)
 - a. After considering several options, the *Radiation Control Program Administrative Procedures Manual* (Manual) was selected as the repository for memorializing all policies and procedures. In the instance of, for example, inspection procedures, the Manual will simply contain a reference to the Radiation Control Program's *Materials Inspection Manual*. In other instances, the policy or procedure will be incorporated into the Manual by December 30, 2011.
2. The review team recommends that the State take measures to ensure that initial inspections are performed at the interval prescribed in IMC 2800. (Section 2.2)
 - a. This recommendation was addressed by adding to the pre-licensing inspection form a step that sets the initial inspection due date to nine months after the license is issued. The immediate fix for handling this in the database is as follows: The "Inspection Priority" will be set to "1" and the "Inspection Date" will be set to the license "Originally Issued" date plus nine (9) months. After the initial inspection, the "Inspection Priority" will be reset to the appropriate priority for the NRC Program Code. A permanent fix will be made with the next database update.
 - b. Consideration is being given to the NRC's LTS DV software as an alternative to our current license tracking system. It may have the capabilities we need. We are working on receiving a copy to review.
3. The review team recommends that the State take measures to ensure that inspection findings are communicated to licensees within 30 days of the date of the inspection. (Section 2.2)
 - a. Bi-weekly Radioactive Materials staff meetings are held on Monday morning to review the status of active inspection reports. These meetings are scheduled using MS Outlook Calendar. If a Monday is a holiday, then the meeting is held on

Tuesday. If the Manager is unavailable, the lead HP convenes the meeting. This will be documented in the Manual by December 30, 2011.

4. The review team recommends that the State take measures to ensure that sufficient information pertaining to inspection observations and identified non-compliances is documented in inspection records and in letters to licensees and that these documents be appropriately reviewed by management, prior to issuance, for thoroughness and consistency. (Section 2.3)
 - a. An inspection-specific check list will be generated for each inspection. The current license, previous inspections, enforcement history, and applicable inspection procedures will be used to generate the inspection check list. This will be incorporated into the *Materials Inspection Manual* by July 29, 2011.
5. The review team recommends that the State obtain additional training (formal and on-the-job, as appropriate) for the Branch manager and members of the technical staff to enhance inspection skills, particularly with regards to: (1) radiation safety issues associated with cyclotron operations, and (2) proper operation and use of radiation survey and measurement instrumentation. (Section 2.3)
 - a. Arrangements have been made with the Minnesota program to inspect the UND cyclotron June 23 while we observe their inspection technique and procedure. Also, we have arranged to visit a same-brand, similar configuration, cyclotron in Minnesota at their convenience.
 - b. Arrangements have been made with the NRC Region IV to accompany their inspectors when they are in South Dakota, Wyoming and Montana. To date NRC has provided two opportunities to accompany inspections in both Wyoming and South Dakota. We have had to pass on both opportunities because we were unable make the arrangements due to flood related activities in the Bismarck-Mandan area. We expect to still make arrangements to accompany NRC inspectors.
 - c. For training in proper operation and use of radiation survey and measurement instrumentation, the applicable sections in ORAU's Applied Health Physics training course, Books 1 and 2 will be used for classroom instruction. Laboratory type exercises will be drawn from the Lab Workbook exercises. The training will be documented in the individual Radiation Control Program - Training Regimen Checklist.
6. The review team recommends that the State take measures to ensure that the Branch's review of licensing actions are adequately documented and that licensing actions are thorough and consistent with the regulations and appropriate licensing guidance. (Section 2.4)
 - a. A request has been made to Region IV through our State Agreement Officer, Rachael Browder, to have an NRC licensing person come to North Dakota to review our process, practices, and license templates for improvements. We will select two or three of the more challenging licenses to review for accuracy and completeness. The final process and procedures will be documented in the Manual with the next update.

- b. Chapter 8 from each of the applicable NUREG-1556 volumes was use to create the license review templates we currently use. This will be documented in the Manual by December 30, 2011.
- 7. The review team recommends that the State provide additional training to the Branch manager and technical staff members regarding technical review of licensing actions, including training to ensure that the staff acquires increased familiarity with: (1) the regulations under North Dakota's equivalent to 10 CFR Parts 30 through 39, and (2) applicable licensing guidance documents for use authorization and license conditions. (Section 2.4)
 - a. It would benefit our licensing activities if NRC would provide training specific to some the more complex licensing actions we have.
 - b. We have obtained copies of applicable license templates and standard conditions from Region IV licensing staff. We have asked NRC Region IV to have someone from their licensing staff come here to help us work through the licensing process using the process/procedures NRC uses.
- 8. The review team recommends that the Branch take measures to determine and document the basis of confidence, through consistent use of the pre-licensing checklist and guidance, that radioactive materials will be used as intended and as described in the application or amendment request, prior to authorizing the material on the license. (Section 2.4)
 - a. The "Pre-licensing Checklist and Implementing Guidance" issued by NRC on September 22, 2008 has been fully implemented as of June 1, 2011. The check lists, along with the instructions, have been provided to the staff and reviewed during a biweekly program staff meeting on May 23, 2011. This change to the licensing process will be incorporated in the Manual by December 30, 2011.
- 9. Regarding financial assurance, the review team recommends that the State: (1) develop a procedure or policy to assess finance assurance requirements as part of significant licensing actions and during licensing renewals; (2) review all North Dakota licenses to determine whether licensees require financial assurance, and either request financial assurance for licenses that are authorized to possess the applicable quantities or revise the license conditions to ensure clear quantity limits that will not require provision of financial assurance; and (3) take measures to ensure that any financial assurance instruments received by the Branch are maintained and stored in accordance with State requirements. (Section 2.4)
 - a. The review for financial assurance has been added to initial license application and any licensing action that adds an isotope or increases the licensed activity. If the license already requires financial assurance, then any isotope change will be reviewed to determine if the action changes the required financial assurance. If any licensing action changes the licensee's financial assurance status, a specific letter will be sent to the licensee addressing the status change. This will be documented in the Manual by December 30, 2011.

- b. Beginning June 1, financial assurance calculations are performed during updating the licenses to include maximum activity per source and maximum possession activity per isotope. Performing the calculations on licenses already updated will be completed no later than October 31, 2011.
 - c. A tracking spreadsheet has been created using templates provided by NRC. The existing financial assurance documents have been logged in and stored in a lock fireproof file cabinet.
10. The review team recommends that the State strengthen its incident response program and take measures to ensure that: (1) reported incidents are consistently evaluated to determine the appropriate type and level of Branch response; (2) licensee event reports are reviewed by the Branch for completeness and appropriate corrective actions; and (3) the Branch's evaluation of licensee events, whether based on a review of licensee reports, on-site reviews, or inspection follow-up, is properly documented to facilitate future follow-up. (Section 2.5)
- a. The Program has acquired the NRC's *Handling of Materials Licensee Event Reports (LERs) by DNMS Staff* (PG9007B.1) to use as a template for handling reported events.
 - b. A full review of how to best use and incorporate this document into our program has not been completed. Once a resolution is reached, training will be provided and documented in the Manual by December 30, 2011.
11. The review team recommends that the State strengthen its allegation program and take measures to ensure that: (1) allegations are promptly evaluated to determine the appropriate type and level of Branch response; (2) the Branch's evaluation of allegations and any actions taken in response to allegations is properly documented to facilitate future follow-up; and (3) processes are in place to provide a response to alleged as appropriate. (Section 2.5)
- a. The plan is to use NRC's DH 8.8 (Management of Allegations) along with NRC's *Allegation Receipt Form* and *Branch Evaluation, Plan & Recommendation* form as the foundation for handling allegations. Once the process and procedure is completed, training will be provided and the process and procedure documented in the Manual by December 30, 2011.

Comment Resolution for the May 31, 2011 email and document from the North Dakota Department of Health (ML111511081) regarding the May 2, 2011, Draft IMPEP Report

- Comment 1: Section 2.1, Paragraph 4, Sentence 4:

Please change "...inspection of a radionuclide production (cyclotron) facility." To read "...inspection of an Academic Type A Broad Scope with an associated medical facility."

Response 1:

Thank you for this comment. The sentence was revised as follows: "Additionally, the Branch manager and one of the former North Dakota technical staff traveled to Minnesota to observe inspection activities."

- Comment 2: Section 3.1, Subsection 3.1.1, Paragraph 2:

This paragraph should read as follows: "One rulemaking action affecting the Radiation Control Program was approved during the review period. Prior to the review period, the Radiation Control Program was funded through license fees as well as obtaining approximately 30-40% of its funding from the State's General Fund. During the past year, the proposed rules were adopted that puts in place a 6-year implementation period for the Radiation Control Program to become fully fee funded. This matter went through the State's rulemaking process including a public comment period. During the implementation period, licensees will receive a fee increase every year for six years. At the end of six years, the Radiation Control Program will be fully fee funded."

Response 2:

Thank you for the comment and clarifying the language used in the paragraph. In the first sentence, the words "piece of legislation" was replaced with "rulemaking action" and the word "passed" was replaced with "approved." In the third sentence, the word "legislation was finalized" was replaced with "the proposed rules were adopted." In the fourth sentence, the word "legislative" was replaced with "rulemaking."

- Comment 3: Section 3.1, Subsection 3.1.1, Paragraph 2:

This paragraph should read as follows: "The review team verified that the State's rulemaking process offers the public and other interested parties an opportunity to comment on proposed regulation changes. The rulemaking process begins with the Branch drafting the proposed rules, which are submitted to NRC for a compatibility review. Concurrently, a public notice is then submitted for publication and public comment in the official newspaper of each of the 53 counties in the State. After a public hearing wherein additional comments can be submitted, any received comments will be evaluated and any necessary changes are made. The proposed rules are then submitted to the State Attorney General for a legal opinion. After the Attorney General's legal opinion is received, the legal opinion and rulemaking package are submitted to the State Health Council for adoption. The package is then submitted to the State's Legislative Council. The Legislative Council submits the package to the Legislative

Rules Committee for final approval. After final approval is received, the Legislative Council publishes the rules. The rules become effective on the date they are published. The Branch Manager indicated that this rulemaking process typically takes 9-12 months.

Response 3:

Thank you for the comment and clarification. Beginning with the 4th sentence of the draft report, the text was replaced with the above clarification beginning with "After a public..." and ending with "...Legislative Council."

ADAMS ML111580527